June 13, 2003

Re: Advisory on Major Incident Reports Involving Gastric Bypass Surgery

Dear Patient Care Assessment Coordinator:

The Medicine Board's Patient Care Assessment (PCA) Committee recently reviewed six Major Incidents Reports involving patients who died within thirty days following gastric bypass procedures. While the cause of death was not determined in all cases, complications associated with these deaths included respiratory compromise, sepsis following leakage from an anastomosis or gastric perforation, and pulmonary embolus. We are sufficiently concerned by this cluster of reports that we are issuing this *PCA Advisory* on the subject of gastric bypass surgery and the reporting of deaths associated with these procedures.

Gastric Bypass Surgery

Given that gastric bypass surgery is only indicated for morbidly obese patients who often present with serious co-morbidities, gastric bypass surgery must be regarded as a major procedure performed on a high-risk population. Institutional policies and procedures in the areas of patient screening and informed consent, credentialing, perioperative and post-operative care and staffing, and quality monitoring should reflect appropriate appreciation of the risks and complications attendant to these surgeries.

Mortality or morbidity rates significantly in excess of appropriate benchmarks should be the subject of careful review, for these or any other procedures.

The PCA Committee of the Medicine Board is continuing its study of Major Incident Reports involving gastric bypass procedures and may issue an *Update* on this topic in the future.

Reporting Major Incidents Involving Gastric Bypass Procedures

Recent discharge data for hospitals in Massachusetts shows a mortality rate of approximately .20 % (two-tenths of one percent) for these procedures. While these data do not reflect mortality and morbidity rates associated with post-discharge complications or readmission for treatment of complications, some surgeons performing these procedures report thirty-day mortality rates in the range of .20% (two tenths of one percent) to .17% (seventeen hundredths of one percent). Other sources cite thirty-day mortality rates slightly higher than 1% (one percent) for these procedures.

Section 3.08 (2) d of the Board's *Patient Care Assessment Regulations* requires that hospitals report deaths as a result of complications from a procedure when the patient's death is "…not ordinarily expected as a result of the patient's condition upon presentation." When surgeons tell patients during the informed consent process that their mortality rates for these procedures are within the range of two percent or less, the message to the patient is that death is not ordinarily expected as an outcome of the procedure. Under those circumstances, *every* death involving these procedures must be reported to the Medicine Board as a Major Incident. Similarly, when benchmark data used at an institution indicates that mortality rates for these procedures at comparable institutions is in the range of two percent or less, death is not ordinarily expected as an outcome of the procedure and every death involving these procedures at the hospital must be reported as a Major Incident.

In issuing this *Advisory* the PCA Committee is not suggesting that events that occur at a higher frequency than two in one hundred should be considered within the range of expected outcomes. Whenever possible, determinations whether an event is "ordinarily expected" should be based on appropriate benchmark data. When experience significantly exceeds expectations based on benchmark data, deaths and major complications also become reportable under the *PCA Regulations*. The intention of the PCA Committee is to illustrate the types of events that clearly are reportable as Major Incidents under the law.

Content of Major Incident Reports Involving Gastric Bypass Procedures

When reporting a Major Incident involving these procedures, institutions should anticipate that the PCA Committee will wish to review information concerning the experience of the surgeon conducting the procedure, including his or her mortality and complication rates for this type of surgery. In addition, the Major Incident Report should be accompanied by a de-identified copy of the patient's informed consent, data concerning the volume of these procedures performed at the hospital, and information concerning the benchmarks used by the medical staff and hospital in monitoring the quality of care provided in connection with these procedures.

If you have any questions concerning this *Advisory*, please contact Michael Kelly, Director of Patient Safety and Quality Improvement Programs at (617) 654-9867 or by email at michael.kelly@state.ma.us

Sincerely,

Martin Crane, M.D.
Chair, PCA Committee